
Declaration of Conformity

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of Medical Devices Directive 93/42/EEC and RoHS Directive 2011/65/EU.

Common name: **ECG & Respiration Transmitter**
Model name: **LX-7120**
Classification: **Class II b** (according to Annex IX of Directive 93/42/EEC)
Categories: **8** (according to Annex I of Directive 2011/65/EU)
Accessories: See Appendix 1
Manufacturer: **Fukuda Denshi Co., Ltd.**
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Location of design: **Fukuda Denshi Co., Ltd. Hongo Office**
2-35-8 Hongo, Bunkyo-ku, Tokyo, Japan
Location of production: **Fukuda Denshi Co., Ltd. Shiroi Factory**
305-1 Naka, Shiroi-shi, Chiba, Japan

Applied Annex: **Annex II** of Directive 93/42/EEC
(Accessories: Annex VII of Directive 93/42/EEC)
Notified Body: **British Standards Institution (0086)**
Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP
United Kingdom
Certificate No.: **CE 01612**

Note: BSI's CE Certificate covers only MDD 93/42/EEC Class IIa and IIb, but not RoHS Directive 2011/65/EU and Class I accessories.

Technical file: No. 063020D-11105, 7th edition

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Common name: **ECG & Respiration Transmitter**

Model name: **LX-7120**

Manufacturer: **Fukuda Denshi Co., Ltd.**

3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan

Location of design: **Fukuda Denshi Co., Ltd. Hongo Office**

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Location of production: **Fukuda Denshi Co., Ltd. Shiroy Factory**

305-1 Naka, Shiroy-shi, Chiba, Japan

Applied Annex: **Annex II** of Directive 2014/53/EU

Technical file: No. 063020D-17612, 1st edition

Date of issue : 16 June 2017

Edition : 7th

First issued : 14 February 2011

A handwritten signature in black ink, appearing to read 'Takashi Nomura', written over a horizontal line.

Takashi Nomura

General Manager

Quality Assurance Department

Following products are in conformity with the provisions of Medical Devices Directive 93/42/EEC and RoHS Directive 2011/65/EU starting with the below mentioned S/N.

Model	S/N
LX-7120	50000788 ~

Appendix 1 (List of Accessories)

Standard Accessories

Common name	Model
Neck Strap	OA-311
4-electrode ECG lead cable	CMT-02HTH-0.8DU
Operation Manual	4L010625C

Related Products

Common name	Model
ECG Hook Type Lead Cable	CMT-01HTH-0.8DU
ECG Hook Type Lead Cable	CMT-02HTH-0.8DU
ECG Hook Type Lead Cable	CMT-03HTH-0.8DU
ECG Clip Type Lead Cable	CMT-01FTH-0.8DU
ECG Clip Type Lead Cable	CMT-02FTH-0.8DU
ECG Clip Type Lead Cable	CMT-03FTH-0.8DU
Disposable case	ABT-710D

